

Appl. No. 10/020,798  
Amdt. Dated Nov. 10, 2003  
Reply to Office Action of June 10, 2003

**Amendments to the claims:**

This listing of claims will replace all prior versions and listing of claims in the application:

Claims 1 - 5 (cancelled)

Claim 7 (cancelled)

Claims 9 - 22 (cancelled)

Claim 23 (amended): A The method according to claim ~~22~~ 36 wherein said protein is selected from the group comprising enzymes, antibodies, antigens, hormones and cytokines.

Claim 24 (amended): A The method according to claim 23 wherein said therapeutically active protein is a hormone.

Claim 25 (amended): A The method according to claim 24 wherein said hormone is insulin.

Claim 26 (amended): A The method according to claim 23 wherein said protein is a cytokine.

Claim 27 (amended): A The method according to claim 26 wherein said cytokine is Factor VIII.

Claim 28 (amended): A The method according to claim ~~22~~ 36 wherein the particle size of said protein is from about 0.01  $\mu$   $\mu$ m to about 10.0  $\mu$   $\mu$ m.

Claim 29 (amended): A The method according to claim 28 wherein the particle size of said protein is from about ~~5.0~~ 0.01  $\mu$   $\mu$ m to about ~~5.0~~ 40.0  $\mu$   $\mu$ m.

Claim 30 (amended): A The method according to claim 29 wherein the particle size of said protein is from about 0.01  $\mu$   $\mu$ m to about 3.0  $\mu$   $\mu$ m.

Claims 31 - 35 (cancelled)

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Claim 36 (new): A method for delivering a therapeutically active protein to the respiratory tract of a patient in need of treatment comprising the steps of:

- a) preparing a liquid carrier vehicle consisting essentially of:
  - i) about 100% v/v substantially anhydrous ethanol; and
  - ii) from about 0.05% to about 5.0% w/v of a pharmaceutically acceptable excipient;
- b) suspending a pharmaceutically effective amount of said protein in said liquid carrier vehicle to produce a suspension;
- c) producing an aerosol of said suspension using an electrohydrodynamic spraying/aerosolization means; and
- d) administering said aerosol to the pulmonary tract of said patient via inhalation of said aerosol.

Claim 37 (new): The method according to claim 36 wherein said substantially anhydrous ethanol contains less than 3.0% v/v water.

Claim 38 (new): The method according to claim 25 wherein said insulin is present in the suspension at a concentration of from about 1.0 mg/ml to about 200.0 mg/ml of said suspension.

Claim 39 (new): The method according to claim 38 wherein the particle size of said insulin is from about 0.01  $\mu\text{m}$  to about 5.0  $\mu\text{m}$ .

Claim 40 (new): The method according to claim 36 wherein said pharmaceutically acceptable excipient is present in said liquid carrier at from about 0.05% w/v to about 5.0% w/v of said liquid carrier.

Claim 41 (new): The method according to claim 40 wherein said pharmaceutically acceptable excipient is a suspending agent.